

**BISMUTH - bismuth subsalicylate liquid**  
**Rij Pharmaceutical Corporation**

*Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.*

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**Drug Facts**

**Active ingredient (in each tablespoon= 15 mL)**

Bismuth subsalicylate 262 mg

**Purpose**

Upset stomach reliever and anti-diarrheal

**Uses**

- relieves upset stomach due to overindulgence in food or drink
- controls diarrhea

**Warnings**

**Reye's syndrome:** Children and teenagers who have or are recovering from chicken pox or flu-like symptoms should not use this product. When using this product, if changes in behavior with nausea and vomiting occur, consult a doctor because these symptoms could be an early sign of Reye's syndrome, a rare but serious illness.

**Allergy alert: Contains salicylate. Do not take if you are**

- allergic to salicylates (including aspirin)
- taking other salicylate products

**Do not use**

- if you have bloody or black stool
- if you have an ulcer or bleeding problem

**Ask a doctor before use if you have**

- fever
- mucus in the stool
- a magnesium-restricted diet
- a sodium-restricted diet

**Ask a doctor or pharmacist before use if you are**

- taking any drug for
- anticoagulation (thinning of the blood)
- diabetes
- gout
- arthritis

**When using this product**

a temporary but harmless, darkening of the stool and/or tongue may occur

## Stop use and ask a doctor if

- symptoms get worse
- ringing in the ears or loss of hearing occurs
- diarrhea lasts more than 2 days

## If pregnant or breast-feeding,

ask a health professional before use.

## Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away.

## Directions

- drink plenty of clear fluids to help prevent dehydration caused by diarrhea
- shake well before using
- use pre-measured cup for accurate dosing
- repeat dosage every 1/2 to 1 hour as needed
- do not take more than 8 doses in 24 hours
- use until diarrhea stops but not more than 2 days
- **adults & children 12 years and over:** 2 tablespoons
- **children under 12 years:** ask a doctor

## Inactive ingredients

Carboxymethylcellulose sodium, D&C Red #3, FD&C Red #40, flavor, glycerin, magnesium aluminum silicate, saccharin sodium, salicylic acid, sodium benzoate, sodium salicylate, sorbitol, water

- Store at room temperature. Protect from freezing and excessive heat (over 40°F or 104°C)
- **each tablespoon (15 mL) contains:** magnesium 32 mg
- **each tablespoon (15 mL) contains:** sodium 24 mg
- **each tablespoon (15 mL) contains:** total salicylate 159 mg
- **TAMPER EVIDENT: Do not use if printed inner cap seal is broken or missing..**

## Principal Display Panel

<b>Drug Facts</b> <b>Active Ingredient (in each tablespoon=15mL)</b> Purpose Bismuth subsalicylate 262 mg ..... {Upset stomach reliever Anti-diarrheal <b>Uses</b> • relieves upset stomach due to overindulgence in food or drink • controls diarrhea <b>Warnings</b> Reye's syndrome: Children and teenagers who have or are recovering from chicken pox or flu like symptoms should not use this product. When using this product, if changes in behavior with nausea and vomiting occur, consult a doctor because these symptoms could be an early sign of Reye's syndrome, a rare but serious illness. <b>Allergy Alert:</b> Contains salicylate. Do not take if you are • allergic to salicylates (including aspirin) • taking other salicylate products. <b>Do not use</b> • if you have bloody or black stool • if you have an ulcer or bleeding problem <b>Ask a doctor before use</b> if you have • fever • mucus in the stool • a magnesium-restricted diet • a sodium-restricted diet <b>Ask a doctor or pharmacist before use</b> if you are taking any drug for • anticoagulation (thinning the blood) • diabetes • gout • arthritis When using this product, a temporary but harmless, darkening of the stool and/or tongue may occur	 NDC 53807-152-08 <b>BISMUTH LIQUID</b> For Upset Stomach Indigestion, Simple Diarrhea and Nausea *This product is not manufactured or distributed by the owner of the registered Trademark Pepto-Bismol®. <b>TAMPER EVIDENT</b> Do not use if printed inner cap seal is broken or missing. <b>8 FL. OZ. (237mL)</b> RIJ PHARMACEUTICAL CORPORATION 40 Commercial Ave. MIDDLETOWN, NY 10941	<b>Drug Facts (continued)</b> Stop use and ask a doctor if • symptoms get worse • ringing in the ears or loss of hearing occurs • diarrhea lasts more than 2 days If pregnant or breast-feeding, ask a health professional before use. Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away. <b>Directions:</b> • drink plenty of clear fluids to help prevent dehydration caused by diarrhea • shake well before using • use pre-measured cup for accurate dosing • repeat dosage every 1/2 to 1 hour as needed • do not take more than 8 doses in 24 hours • use until diarrhea stops but not more than 2 days • <b>adults &amp; children 12 years and over:</b> 2 tablespoons • <b>children under 12 years:</b> ask a doctor <b>Inactive ingredients:</b> Carboxymethylcellulose sodium, D&C Red #3, FD&C Red #40, flavor, glycerin, magnesium aluminum silicate, saccharin sodium, salicylic acid, sodium benzoate, sodium salicylate, sorbitol, water Store at room temperature. Protect from freezing and excessive heat (over 40°C or 104°F) • <b>each tablespoon (15 mL) contains:</b> magnesium 32 mg • <b>each tablespoon (15 mL) contains:</b> sodium 24 mg • <b>each tablespoon (15 mL) contains:</b> total salicylate 159 mg Rev. 1210-15208  N 3 53807-152-08 4
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**BISMUTH**

bismuth subsalicylate liquid

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:53807-152
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
BISMUTH SUBSALICYLATE (UNII: 62TEY51RR1) (BISMUTH CATION - UNII:ZS9CD118YE)	BISMUTH SUBSALICYLATE	262 mg in 15 mL

### Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
FD&C RED NO. 3 (UNII: PN2ZH5LOQY)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SALICYLIC ACID (UNII: O414PZ4LPZ)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM SALICYLATE (UNII: WIQ1H85SYP)	
SORBITOL (UNII: 506T60A25R)	
WATER (UNII: 059QF0KO0R)	

### Product Characteristics

<b>Color</b>	pink	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	PEPPERMINT	<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53807-152-08	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/16/1999	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part335	03/16/1999	

**Labeler** - Rij Pharmaceutical Corporation (144679156)

## Establishment

Name	Address	ID/FEI	Business Operations
Rij Pharmaceutical Corporation		144679156	manufacture(53807-152)

Revised: 4/2018

Rij Pharmaceutical Corporation